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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,400	02/20/2002	Michael Young	10275-041002	3033

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EXAMINER
WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,400	YOUNG ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *May 6, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26,46 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26,46 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2/8/02
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application filed February 20, 2002, is a divisional of 09/333,213 filed June 15, 1999, now US Patent 6,548,653, which claims benefit to 60/089,343 filed June 15, 1998.

Applicants' amendment filed with the response to the restriction requirement has been received and entered. Claims 51 and 52 have been canceled.

Claims 1-26, 46 and 47 are pending.

Election/Restriction

Applicants have elected group I, claims 1-26, 46 and 47, drawn to a erythropoietin serum albumin fusion protein without traverse. Claims 51 and 52 encompassing the non-elected invention have been canceled. Claims 1-26, 46 and 47 are pending and currently under examination.

Specification

The nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825. More specifically, 37 CFR 1.821(d) states: "[w]here the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description of claims, even if the sequence is also embedded

in the text or the description or claims of the patent application. For example, all sequences on page 6 should be identified by a SEQ ID NO next to the protein sequences. In addition it is noted that drawing 1 contains a similar sequence that is not identified in the drawing nor the brief description. Applicant's attention is directed to the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

It is noted that Applicants have requested that the sequence information from 09/333,213 be transferred to the instant application (paper filed May 6, 2004), however this does not address the deficiencies in the specification and drawings.

Appropriate correction is required.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

Drawings

New corrected drawings are required in this application because the drawings contain a protein sequence that is not identified by SEQ ID NO.

Please note that the corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings **will not be held in abeyance.**

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-26, 46 and 47 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 56-81, 88-101, 106-111 of copending Application No. 10/768,873 Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims encompass the same EPO-SA fusion protein with methods of making and using that have only one obvious use in making said fusion proteins.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-26, 46 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claims 1-26, 46 and 47 are unclear in the

recitation of "an EPOa-hSA" because it is unclear if the EPOa is from one species or from any species. Secondly, it is unclear if the EPOa encompasses the full uninterrupted coding region or if portions of EPO can be substitutes or disrupted with the hSA. The description of the EPOa-hSA in the specification recites several amino acid changes to disrupt the glycosylation of the protein, however it is not clear if the specifically numbered amino acids are the human EPO amino acids or from another species, or if these specific amino acids occur in all EPO (entire specification, for example page 1; lines 22-33). With respect to the arrangement of the fusion protein several preferred embodiments of the arrangement of the EPOa-hSA and potential analogs or biologically active fragments of EPO are recited, however is not very clear from the recitation if 'EPOa-hSA' if all these arrangements are meant to be claimed and within those arrangements if portions and analogs of EPO are also encompassed (entire specification, for example page 1; lines 18-21 and pages 5-6; lines 29-12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-26, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bill *et al.* (BBA, 1995), Bill *et al.* (BBA, 1997), Korhonen *et al.* (European Journal of Biochemistry 245:482-489, April, 1997), and Syed *et al.* (all references listed in IDS).

Claims 1-26, 46 encompass a EPO-serum albumin fusion protein wherein the EPO sequence has been modified to delete potential glycosylation sites. Claim 47 is drawn to a method of using said protein in a patient who would benefit from the affect of EPO.

Bill *et al.* (both references) teach nucleic acid sequences that encode human and mouse EPO (page 37; column 1). Each of the EPO sequences were modified at the glycosylation sites of the encoded protein (pages 37-38; columns 2-1). Bill *et al.* and Korhonen *et al.* teach methods of making an EPOa fusion protein, however the fusion protein Bill *et al.* produce is an EPOa-GST fusion protein. Syed *et al.* teach a recombinant protein genetically fused to serum albumin and methods to produce the protein in COS cells (page 3244-Material and Methods and summary of N and C terminal constructs on page 3246; figure 3A). Syed *et al.* teach that fusion proteins made with serum albumin are more stable and cleared more slowly when administered to a subject. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the isolated nucleic acid encoding EPOa and the methods of Bill *et al.* and the expression constructs and methods of Syed *et al.* to produce an EPOa-hSA fusion protein. One having ordinary skill in the art would have been motivated to generate an EPOa fusion protein, a secreted protein found in the circulation as described by Bill *et al.* or Korhonen *et al.* with the methodology and materials disclosed by Syed *et al.* in order to produce a fusion protein which is cleared more slowly than EPOa alone from the circulation

(Syed et al. page 3243; top of second column). Given the state of the art at the time the invention was made, there would have been a reasonable expectation of success to substitute EPOa described by Bill *et al.* or Korhonen *et al.* for hirudin to create an expression construct and express an EPOa-serum albumin fusion protein with the methods described by Syed *et al.* Further, there would have been a reasonable expectation of success to substitute the nucleic acid encoding SA into the vector described by Bill *et al.* for expression in *E. coli* and generating an EPO-SA fusion protein (page 26; lines 29-34).

Thus, the claimed invention as a whole was clearly *prima facie* obvious.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

Joe Woitach

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